



California Medical Device Recall Information



Recall Name

SynCardia Systems Recalls Freedom Driver Systems Due to Potential for the Device to Stop Pumping

Recall Date	Product Description	Recalling Firm	Recall Reason
08/06/15	Freedom Driver Systems used with the SynCardia temporary Total Artificial Heart (TAH-t)	SynCardia Systems, Inc. Tucson, AZ	<i>A specific part of the Freedom Driver drive mechanism may fail and cause the device to stop pumping.</i> <i>If the Freedom Driver stops pumping, the patient will lose consciousness almost immediately. The patient will likely experience serious injury or death if not immediately switched to a backup driver by a caregiver.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Serial Numbers (S/N): <ul style="list-style-type: none">• 85978 (S/N 85978-001 through 85978-040)• 85979 (S/N 85979-001 through 85979-040)	CA , nationwide	Manufactured from: Nov. 3, 2014 to July 29, 2015 Distributed from: Nov. 10, 2014 to July 29, 2015

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm463300.htm>